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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,542	11/28/2001	John Shutter	00-658-A	9323

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EXAMINER	
BASI, NIRMAL SINGH	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/995,542	SHUTTER ET AL.	
	Examiner	Art Unit	
	Nirmal S. Basi	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-58* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. ***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 10-11, 44-46, 57-58, drawn to isolated nucleic acid, expression vector comprising said DNA and method of preparing polypeptide using a cell containing said vector classified in class 536, subclass 23.1, for example .

II. Claims 9, 13-17, 38-43, 47-48, drawn to isolated polypeptide, classified in class 530, subclass 350.

III. Claims 18-32, 34-35 and 37, drawn to antibody, classified in class 530, subclass 387.9, for example.

IV. Claims 55 drawn to transgenic non-human animal, classified in class 800, subclass 2, for example.

V. Claims 12, drawn to a process for determining whether a compound inhibits ABCL polypeptide activity comprising exposing a cell according to claims 5, 6 or 7 to a compound and measuring ABCL polypeptide activity, classified in class 435, subclass 7.21 for example.

VI. Claims 33, drawn to a method for treating, preventing, or ameliorating an ARCL polypeptide-related disease, condition, or disorder comprising administering to a patient an effective amount of a selective binding agent according to Claim 18, classified in class 514, subclass 2 for example.

VII. Claims 36, drawn to a method of detecting or quantitating the amount of ABCL polypeptide using the anti-ABCL antibody or fragment of Claim 18, classified in class 435, subclass 7.1, for example.

VIII. Claims 49, drawn to a method for treating, preventing, or ameliorating an ARCL polypeptide-related disease, condition, or disorder comprising administering to a patient an effective amount of the polypeptide of any of the claims 13, 14 or 15, classified in class 514, subclass 2 for example.

IX. Claims 50, drawn to a method of diagnosing a pathological condition or a susceptibility to a pathological condition in a subject comprising determining the presence or amount of expression of the polypeptide of any of Claims 13, 14, or 15, or the polypeptide encoded by the nucleic acid molecule of any of Claims 1, 2, or 3 in a sample; and diagnosing a pathological condition or a susceptibility to a pathological condition based on the presence or amount of expression of the polypeptide, classified in class 435, subclass 7.1 for example.

X. Claim 51 drawn to a device, comprising a membrane suitable for implantation and cells encapsulated within said membrane, wherein said cells secrete a protein of any of Claims 13, 14, or 15., and said membrane is permeable to said protein and impermeable to materials detrimental to said cells, classified in class 424, subclass 1.21.

XI. Claims 52-53 drawn to a method of identifying a compound that binds to an ABCL polypeptide classified in class 435, subclass 7.1.

XII. Claim 54, drawn to a method of modulating levels of a polypeptide in an animal comprising administering to the animal the nucleic acid molecule of any of Claims I , 2, or 3, classified in class514, subclass 44.

XIII. Claim 56, drawn to a process for determining whether a compound inhibits ABCL polypeptide activity or ABCL polypeptide production comprising exposing a transgenic mammal according to Claim 55 to the compound, and measuring ABCL polypeptide activity or ABCL polypeptide production in said mammal., classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons.

Inventions I-IV are patentably distinct products.

The polypeptide of group II and polynucleotide of group I are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. The polypeptide of group II can made by chemical synthesis or recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of groups I and II are patentably distinct.

Furthermore, searching the inventions of groups I and II together would impose a

serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. It would be burdensome to search the inventions of groups I and II together.

The polypeptide of group II and the antibody of group III are patentably distinct for the following reasons:

While the inventions of both group II and group III are polypeptides, in this instance the polypeptide of group II is a single chain molecule that functions as an enzyme, whereas the polypeptide of group III encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of group II and the antibody of group III are structurally distinct molecules; any relationship between a polypeptide of group II and an antibody of group III is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope

of the antibodies that would be generated upon immunization with the polypeptide. Therefore the polypeptide and antibody are patentably distinct.

Furthermore, searching the inventions of group II and group III would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of group III. Furthermore, antibodies which bind to an epitope of a polypeptide of group II may be known even if a polypeptide of group II is novel. In addition, the technical literature search for the polypeptide of group II and the antibody of group III are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The polynucleotide of group I and the antibody of group III are patentably distinct for the following reasons. The antibody of group III includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs). Polypeptides, such as the antibody of group II which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid

sequence of the encoded polypeptide. In the present claims, a polynucleotide of group I will not encode an antibody of group III, and the antibody of group III cannot be encoded by a polynucleotide of group I. Therefore the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of group I and group III would impose a serious search burden since a search of the polynucleotide of group I is would not be used to determine the patentability of an antibody of group III, and vice-versa.

The products of Inventions I-IV are distinct because they have distinct functional, chemical and physical properties and are capable of separate use and manufacture.

Inventions V-IX and XI-XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The methods of groups V-IX and XI-XIII are all unrelated as they comprise distinct steps, utilize different products and have different goals, which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Therefore, each method is divergent in materials and steps. For these reasons the Inventions V-IX and XI-XIII are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups V-IX and XI-XIII have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups V-IX and XI-XIII together.

The polynucleotide of Inventions I and the method of Inventions XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of group I can be used to make recombinant proteins as opposed to its use in diagnosing an autoimmune disease.

Searching the inventions of Groups I and XII together would impose serious search burden. The inventions of Groups I and XII have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polynucleotides and the method of group XII are not coextensive.

Only the product of Invention I is related the method of Invention XII, all other methods disclosed above are unrelated to Group I because the product of group I is not used or otherwise involved in said unrelated methods.

The polypeptide of Inventions II and the method of Inventions V, VII-IX and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as

claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide can be used to catalyze an enzymatic reaction or to produce antibodies.

Searching the polypeptide of Inventions II and the method of Inventions V, VII-IX and XI together would impose serious search burden. The inventions of Groups II and V, VII-IX and XI have a separate status in the art as shown by their different classifications.

Only the product of Invention II is related the method of Inventions V, VII-IX and XI, all other methods disclosed above are unrelated to Group II because the product of group II is not used or otherwise involved in said unrelated methods.

Inventions II and V, VII-IX and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II can be used to immunize an animal to produce an antibody

Inventions III and VI-VII, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used to produce secondary antibodies for use in immunoassays

Searching the inventions of Groups III and VI-VII, together would impose serious search burden. The inventions of Groups III and VI-VII have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the antibodies and the method of group VI-VII are not coextensive.

Only the product of Invention III is related the method of Invention VI-VII, all other methods disclosed above are unrelated to Group IIII because the product of group III is not used or otherwise involved in said unrelated methods.

The product of Invention IV is unrelated to Group VI-IX, XI-XIII because the product of group IV is not used or otherwise involved in said unrelated methods.

Inventions X and I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are structurally and chemically different. Invention X is an apparatus which neither makes or uses the products of inventions I-IV.

The apparatus of Inventions X and the method of invention V-IX and XI-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions

are structurally and chemically different. Invention X is an apparatus which neither is neither used or made by the methods of inventions I-IV.

The inventions of Groups I-XII are distinct it would be burdensome to search any combination of the inventions of Groups I-XII together.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March

26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The claims of Group I-XII are drawn to a multitude of nucleic acids, SEQ ID NOs: 1, 4, 7, proteins SEQ ID NO:2, 3, 5, 6, 8 and methods which use of said nucleic acids, or of use of their encoded polypeptides or cells containing said polypeptides. The claims apply to numerous structurally and functionally different nucleic acids and their encoded polypeptides. This constitutes recitation of an implied, mis-joined Markush group that contains multiple, independent and distinct inventions. Each of the different nucleic acids/polypeptides/antibodies/and methods of use are independent and distinct because no common structural or functional properties are shared.

There is no description of definitive structural or functional features of the claimed Markush group. The Markush group contains no conserved regions which is critical to the structure and function of the genus claimed. The common function of the claimed genus of polynucleotides, which is based upon a common property or critical technical feature of the genus claimed is not disclosed. Accordingly, these claims are subject to restriction under U.S.C.§ 121. Upon election of Groups I-XII, Applicants is additionally required to elect a

single nucleic acid encoding its respective protein . This requirement is not to be constructed as a requirement for election of species, since each of the compounds recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal S. Basi whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nirmal S. Basi
Art Unit 1646
September 30, 2004

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